A DEVICE AND METHOD OF TREATMENT FOR FOOT CARE

The present invention pertains to a device for the treatment of a foot, particularly to alleviate hammertoe, hallux valgus and similar complaints. The device includes a relatively stiff upper support with an extension at the front portion of the foot of at least two toes and covered against the toes with padding, the support being adjustably positioned in place such, that the upper support presses the toes against a surface below the toes.
A DEVICE AND METHOD OF TREATMENT FOR FOOT CARE

The invention concerns a device for caring for the feet, in particular for alleviating hammertoe, hallux valgus and similar complaints.

Even a healthy person's foot can show signs of position errors independent of age. These can be congenital, due to illness, acquired or an after-effect of trauma. Manipulation, motor treatment, aids and surgical treatment are the forms of treatment employed. The commonest incorrect positions of the toes are hammertoe (digitus malleus or digitus hamatus) and hallux valgus. The aforesaid can occur either separately or together. Hammertoe can be caused by neurological factors, illnesses such as diabetes and arthritis, or by incorrect positions of the foot and ankle. The use of shoes that are too short or narrow can also cause hammertoe. Hallux valgus can be caused by hereditary predisposition, the wearing of unsuitable shoes and by a fall in the transverse arch of the foot. In all age-groups, hallux valgus is three times more common in women than in men.

The use of aids and motor treatments are to be recommended until movement occurs in the joint. However, surgical treatment is the only option whenever the toe joints have become completely dislocated and there is no longer any movement in them. Nevertheless, surgical treatment is expensive and felt to be difficult. Time has to be set aside for recovering from the operation.

Treatment using toe-straighteners is based on biological laws, the functional adaptation of the bone presented by Wolfe and the functional adaptation of the soft tissues presented by Davis. If the toes are kept for long enough in the wrong position, they have a tendency to stay in that position and, correspondingly, whenever the toes are placed in the correct position and kept there, they have a tendency to straighten out if they have not become completely stiffened.

When an aid is used, it is regarded as an advantage if the user is able to fit the aid personally or at least with someone else's assistance. For this reason, it is necessary for the aid to be simple and easy to use. However, the aid ought not to be
inconvenient or even hazardous. For example, the sense of feeling in the feet of
diabetes patients may be impaired. In that case, there exists the possibility that the
unsuitable use of an aid may result in skin damage and circulatory disorders. In cases
of this kind, the patient needs to discuss the use of the aid with the physician and the
situation needs to be observed more often than usual. It is recommended that regular
visits to the chiropodist be arranged to prevent ulcers and other similar troubles.

Whenever the toes have been in an incorrect position for a long time, it also takes a
long time to correct them than is the case with fairly recent incorrect positions. It has
been observed that the younger the person, non-congenital incorrect positions are
corrected more quickly than in elderly persons. Corrective treatment is also more
effective the longer the patient uses aids. For this reason, an aid ought to be employed
as much as possible and thus preferably whenever it is possible for the patient to use
one. It is often very beneficial if, in addition to an aid, the patient receives motion
treatment of the foot, massage, muscle and tendon stretching and instructions for
independent exercising of the foot.

Numerous ways of treating feet with mechanical devices are known in the sector, e.g.,
using corrective and support devices, special shoes, what are known as toe fillers and
individual orthoses. Publication US 963,605 presents a shoe in which each toe has its
own compartment by means of a kind of partition. This enables a very typical type of
position error of the toes to be corrected, albeit often with quite modest results.
Publication US 1,245,468 presents an arrangement whereby the big toe is turned back
away from the direction of toe number 2 by means of a support sleeve and strap.
Publication US 730,366 presents a support placed in the sole of the shoe which
enables the big toe to be kept in its correct position. A virtually identical solution, for
the treatment of hallux valgus complaints in particular, is presented by publication JP
6062906. Publication US 1,349,095 presents toe spaces tied to the shoe by means of
shoelace loops which pass through the sole of the shoe, but a device of this kind is
difficult to use, at least for the person to fit personally. Publication DE 928 087
presents a sheath-like device, which supports the big toe and can be directed
adjustably towards the side, for use in a special shoe. US 3,299,893 present
arrangements whereby the foot can be prevented from moving forward in the shoe.
An adjustable support collar is positioned on top of the foot. There is also a support piece in the inner sole of the shoe. This piece can even be spring-loaded and rises up from the sole, extending to several toes but not the big toe. Publication 4,263,902 presents a device arranged in the shoe for treating hammertoes, albeit the arrangement is quite complicated and calls for the use of a special shoe. The required force, which presses the support downwards, is transferred from the heel via a separately fixed axle. The force only has an effect when the person is walking. Publication US 4,393,876 also presents a device that is fastened firmly to the shoe, i.e., the arrangement calls for the use of a special shoe. Here, too, the force which presses the upper support downwards, is transferred from the heel. The force only has an effect when the person is walking. The arrangement presented in publication 4,475,927 also calls for the use of a special shoe manufactured for that specific purpose.

The purpose of the invention is to present a device for treating the foot. This device for treating hammertoe, hallux valgus complaints and similar problems and for alleviating symptoms can be used to get the correct position of the toes maintained at least for the duration of the treatment period. If the treatment with the device continues for long enough, the position faults in the toes have a tendency to be corrected. Usually the patient is personally able to use the device according to the invention effectively in the treatment of personal foot complaints. The particular purpose of the invention is to present an adjustable device with which in most cases the patient can personally adjust the intensity of the effect caused by the device and also take into account what the foot feels. One purpose of the invention is to present a device which would be very small in size and which could even be used in an ordinary shoe without special measures. In that case, the effect of the device could, however, be adjusted in certain cases even though, e.g., some kind of toe sock or shoe were on the foot underneath the device throughout the adjustment. The use of a sock also reduces the need for paddings in the device. In addition, one purpose is for the patient to be able if necessary to use the device for as long as possible, also when the patient is asleep and even in certain jobs if the patient is in working life. The purpose is also to use the device for immobilisation, i.e., the joints of the toes are rendered immobile in the aftertreatment of, e.g., a sprain or fracture. The aim is also for the device to be employed for the prevention of deformity in the treatment of certain
illnesses. The device can also be used, e.g., in an open-toed sandal in such a way that the device is fitted through the insole of the sandal so that the sheet-like lower support of the device is underneath the sole of the sandal, the tightening screw passes through the sandal and the upper support of the sandal is positioned inside it. This slender device can also be fitted as it is inside an ordinary shoe.

The purpose of the invention is achieved by means of a device which includes a relatively stiff upper support which extends to the toes or at least two toes and is covered with padding placed against the toes. As the said upper support is separate from the shoe and can be fitted in such a way that it can be adjusted into place so that the upper support presses the toes against the surface below the toes, the patient himself or at least the person treating him can adjust the pressing effect on the toes so that it is as effective as possible. Nevertheless, the patient can without undue pain keep the device in place for the duration of one treatment period, which can also be long. However, care must always be taken to ensure that the device is not adjusted so tightly that it causes inconvenience to health.

As the force of the upper support pressing the toes can be increased or decreased during the treatment period by means of at least one adjusting element, the result is an effective form of treatment in which the pressing force can be increased after some time. In acquired hammertoe in particular, the incorrect position has been formed gradually and so it is good for correction to be performed gradually over a period. Usually, greater force accelerates the treatment result. However, if the patient then feels that the pressing force is too great, the pressing force can of course be reduced by means of the adjusting element at any time.

As the force of the upper support pressing the toes can be increased or decreased steplessly, the adjustment of the pressing force can take place even quite slowly and a bit at a time, i.e., with gradual increases according to what the patient feels. The feeling in the feet of some patients is impaired or absent, and so the adjustments must be made with particular care.
It is recommended that there be a mainly sheet-like and relatively stiff lower support below the toes which is covered with padding on at least its upper surface unless the material itself is sufficiently soft. The lower surface by the toes then receives effectively with the upper support the joint effect pressing the treated area. The said padding can be, e.g., shoe insole material or some other flexible and elastic but non-allergenic material or similar.

As the force of the upper support pressing the toes is achieved by means of a regulating screw, it is very easy for virtually anyone to tighten the regulating screw. If the base part of the regulating screw is shaped to be like, e.g., a wing nut or to be large in diameter, in particular a serrated cylinder, the adjustment can be performed without special tools and quite effortlessly and quickly.

As the regulating screw is positioned in the area between toes no. 1 and no. 2, the regulating screw is in a particularly suitable spot as regards strength of materials and anatomy. As the space between toes no. 1 and no. 2 is thus meant to be rendered and also made to remain fairly large, the regulating screw is in a particularly good spot as regards use of space, too. Usually this point is the highest and most spacious part in the front of shoe, too.

It is possible that at least part of the force of the upper support pressing the toes can be obtained by means of at least one Velcro tape. If the Velcro tape is arranged when tightened to press the upper support downwards, the result is an adjustable structure in which the force pressing the upper support downwards can be selected as required and adjusted where necessary to be smaller or greater during the treatment period.

It is also possible for the device to have a regulating screw and also an adjustable Velcro tape joining the upper support and the lower support near toe no. 5. In this case, the effective and adjustable pressing effect of the upper support and also the pressing effect near toe no. 5, which is based on the Velcro tape and its adjustable tightness, can be taken advantage of.
Alternatively, the upper support and the lower support can be attached adjustably to each other from near toe no. 5 by means of a joint or similar. In this case, the joint can also be of an adjustable structure, and so the device is then adjustable, even from two points. It is possible that fitting the device personally to one’s own foot for the treatment period is sufficiently easy for most people and usually at least whenever the said connection is a jointed connection.

If the device incorporates guide elements which prevent rotational motion between the upper support and the lower support, the upper and lower parts of the device can be made to remain in the desired position in relation to each other even if the device according to the invention is in use which only has a regulating screw joining the upper and lower parts.

The invention is described in the following in greater detail with reference to the drawing, in which

- Figure 1 presents the device for treating feet according to the invention when the device is assembled, viewed from the front of the foot towards the back of the foot,
- Figure 2 presents the device according to Figure 1 viewed from above,
- Figure 3 presents the top of the device according to Figure 2 from the direction A-A in a partial cross-section,
- Figure 4 presents the device according to the invention in use in a shoe,
- Figure 5 and partial visualisation 5a present an upper support to be used in connection with the device according to the invention and
- Figure 6 presents an adaptation of the device according to the invention.

In the drawing, reference number 1 refers to a device for treating the right foot. If the left foot needs to be treated, a device that is like a mirror image needs to be employed. Device 1 includes upper support 1 and lower support 3, which are made from relatively stiff material, e.g., stainless sheet steel, aluminium, steel or plastic such as Kevlar, which as a material is lighter than steel or metals and easier to work. Upper support 2 and lower support 3 are joined by regulating screw 4, whose upper end 5 is meant to be adjusted without a tool. Where necessary, upper end 5 can be, e.g.,
serrated and cylindrical, very low or higher, like a fairly large wing nut for people with weak hands, or of some other shape that is observed to be suitable. Regulating screw 4 is positioned in the area between toes 1 (reference number 11) and 2 (reference number 12) near to the rear of the area between the toes. At the lower end of regulating screw 4 is a fairly long sleeve 6 fastened to lower support 3 and incorporating an internal thread (not shown). The descending part of upper end 5 is screw 7, which incorporates an external thread of the same size as the internal thread of sleeve 6. The operating principle of regulating screw 4 is to tighten upper support 2 and lower support 3 in relation to each other with the required force and to keep the said parts at the required distance from each other until the next adjustment. Figure 1 shows that bent support piece 8 made from sheet steel is fastened to upper support 2 and incorporates a hole for sleeve 6. Support piece 8 extends from point 11 of toe 1 to point 12 of toe 2, and also even further.

Support piece 8 and upper support 2 are fastened firmly to each other by means, e.g., of point welding (not shown). Toes no. 3, no. 4 and no. 5 are inside device 1 at reference numbers 13, 14 and 15. At the end of lower support 3 is ascending bend 9, which end 10 of upper support 2 can be fastened adjustably to. The lower surface of upper support 2 and correspondingly of support piece 8 is covered with padding 16, which can be, e.g., 1-2 mm in thickness. The upper surface of lower support 3 is covered with padding 17 and the upper surface of lower support 3 is covered with padding 18, which, e.g., when walking without shoes and when device 1 is fitted, touches the floor. Device 1 is used in such a way that regulating screw 4 is turned in the open direction but preferably not entirely loose. Bend 9 is jointed to end 10. The toes of the foot are placed correspondingly in points 11-15 and the device is adjusted into place so that the force of the upper support pressing the toes acts on the toe joints. Sleeve 6 is positioned near the rear of the space between toes no. 1 and no. 2. Regulating screw 4 is used by turning screw 7 from upper end 5 more tightly, under the effect of which upper support 2 and support piece 8 begin to press lower support 3 against the toes. The effect of turning is observed and turning must not continue so much that the force squeezing the toes becomes excessive. If necessary, regulating screw 4 is turned open to some extent. Later, the squeezing effect can be stepped up to render treatment more effective.
Figure 2 shows that upper support 2 is shaped to suit the shapes of the toes. Upper support 2 presses the toes from the top and the pressing effect is also often not necessary nor desirable from the very front of the toes, i.e., near the nails. As toe no. 1 is often higher than the other toes, it is advantageous to shape the descending part of upper support 2 to toe space 12. That is why device 1 should be raised only a little from (at) toe spaces 13-15, and so device 1 can be suited very well, when fitted to the foot, to a slightly loose-fitting shoe or at least from (at) the front to an open shoe.

Figure 3 presents the end of device 1 according to Figure 2 from the direction A-A in a partial cross-section. End 10 has been slipped for the sake of example into gap 9a arranged in bend 9. There can be several gaps (19a, 19b, 19c, 19d etc.), so that the device could be adjusted not only by means of regulating screw 4 but also from the other end, i.e., from near the little toe.

Figure 4 presents device 1 according to the invention in use in shoe 20. Only the front of the foot is shown. Device 1 is suited particularly well for use for treating the foot in shoe 20 of the kind shown in Figure 4, in which its front is entirely open and the space at the front of shoe 20 can be adjusted with clasp 21 or similar. As the front is open, regulating screw 4 can be used without taking the shoe off the foot. According to one advantageous form of application of the invention, shoe 20 is made so that lower support 3 is only a sheet-like piece, which is positioned underneath the insole of shoe 20. Sleeve 6 is fastened to lower support 3, and a hole has been made for sleeve 6 in the insole of shoe 20 between toes no. 1 and no. 2. In this case, the arrangement is very simple because the foot is only placed in shoe 20, upper support 2 is fitted and regulating screw 4 is used to tighten upper support 2 to press the toes with a force that is deemed suitable.

Figure 5 presents upper support 22 according to one form of application of the device according to the invention, which is largely like upper support 2 but is shorter and intended to settle only by toes no. 1, 2 and 3. Points 11, 12 and 13 are for these and are formed with the aid of support piece 8 and padding 16. For regulating screw 4, there is a hole in upper support 22 and in its support piece 8 at point 23. Upper support 22 can be used in the shoe of Figure 4 instead of upper support 2 in particular
in the event that the force pressing toes no. 4 and 5 is not required but the position of
toes no. 1 and no. 2 needs to be corrected. Figure 5a presents hole 28 for sleeve 6 in
support piece 8. Also in the vicinity of hole 28 are holes 29a and 29b, through which
in this form of application are fitted the guide pins (not shown), which are fastened
firmly close to sleeve 6 of lower support 3. Owing to these guide pins, upper support
22 remains very reliably in the correct direction when device 1 is used. The rotational
motion between upper support 22 and lower support 3 can of course be prevented by
means of many other solutions. One means to be recommended would be to make
sleeve 6, e.g., square in cross-section and the corresponding hole also square.

Figure 6 presents device 1 for treating the foot according to one form of application of
the invention. Upper support 24 is like the earlier upper support 2, but does not
include end 10. Lower support 25 is like the earlier lower support 3 but does not
include gaps 19a-d nor necessarily even bend 9. Velcro tape 26 is fastened to the
lower surface of lower support 25 and its counterpiece 27 is fastened near the end of
upper support 24. Velcro tape fastening (26,27) replaces the adjustable jointed
structure (9, 10, 19a-d), presented in Figures 1-3, and nevertheless the tightness
between upper support 24 and lower support 25 can be adjusted easily and steplessly
from this end in addition to the tightening by means of regulating screw 4. Velcro tape
fastening (26, 27) keeps the free ends of upper support 24 and lower support 25 at the
same places in relation to each other, and regulating screw 4 keeps the other end in
place. Velcro tape fastening can also be applied in shoe 20 presented in Figure 4 in
such a way that Velcro tape 26 is fastened to the sole structure of shoe 20 and that
counterpiece 27 is fastened to upper support 22 or 24.

The invention is not restricted to the forms of application presented but several
adaptations of it can be perceived within the framework of the enclosed claims.
LIST OF REFERENCE NUMBERS

1 device for treating foot 1
2 upper support 2
3 lower support 3
4 regulating screw 4
5 upper end 5
6 sleeve 6
7 screw 7
8 support piece 8
9 bend 9
10 end 10
11 section 11 of toe 1
12 section 12 of toe 2
13 section 13 of toe 3
14 section 14 of toe 4
15 section 15 of toe 5
16 padding 16
17 padding 17
18 padding 18
19 gap 19
20 shoe 20
21 clasp 21
22 upper support 22
23 point of hole 23
24 upper support 24
25 lower support 25
26 Velcro tape 26
27 counterpart
28 hole 28
29 holes 29a, 29b
Claims

1. A device (1) for the treatment of a foot, particularly for alleviating hammertoe, hallux valgus and similar complaints, the device (1) comprising a relatively stiff upper support (2, 22, 24) with an extension of at least two toes, wherein said upper support (2, 22, 24) is separate from the shoe and it can be adjustably fitted in place such, that said upper support (2, 22, 24) presses the toes against a surface below the toes.

2. Device (1) according to claim 1, wherein the upper support (2, 22, 24) is covered with padding.

3. Device (1) according to claim 2, wherein the upper support (2, 22, 24) has a shape at least in part coinciding with the shape of the toes.

4. Device (1) according to claim 3, wherein the force exerted on the toes by the upper support (2, 22, 24) can be increased or decreased during the period of treatment by means of at least one control means.

5. Device (1) according to claim 4, wherein the force exerted on the toes by the upper support (2, 22, 24) can steplessly be increased or decreased.

6. Device (1) according to any one of the preceding claims, wherein there is a generally plate-like and relatively stiff lower support (3, 25) below the toes, said support being covered with padding (17) at least on its upper surface.

7. Device (1) according to claim 6, wherein the force exerted on the toes by the upper support (2, 22, 24) is achieved by means of a regulating screw (4).

8. Device (1) according to claim 7, wherein the regulating screw (4) is located in a space between toes no. 1 and no. 2.

9. Device (1) according to claim 6, wherein at least part of the force exerted on the toes by the upper support (2, 22, 24) is achieved by means of at least one Velcro tape (26).
10. Device (1) according to any one of the preceding claims, wherein the device (1) includes a regulating screw (4) and additionally an adjustable Velcro tape close to toe no. 5 connecting the upper support (2, 22, 24) and the lower support (3, 35).

11. Device (1) according to any one of the preceding claims, wherein the upper support (2, 22, 24) and the lower support (3, 25) are adjustably mutually connected close to toe no. 5 by means of a joint or the like.

12. Device (1) according to claim 8, wherein guide means prevent a twisting movement between the upper support (2, 22, 24) and the lower support (3, 25).

13. Method for treating a foot, particularly to alleviate hammertoe, hallux valgus and similar complaints, the method involving the positioning of the foot into a device (1) including a relatively stiff upper support (2, 22, 24) with an extension of at least two toes, the method comprising that the upper support (2, 22, 24), which is separate from a shoe, is positioned in place and the upper support (2, 22, 24) is adjusted such, that it presses the toes against a surface below the toes.
Fig. 5

Fig. 5a

Fig. 6

SUBSTITUTE SHEET (RULE 26)
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61F 5/01, A43B 7/26
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A43B, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Further documents are listed in the continuation of Box C. See patent family annex.

Date of the actual completion of the international search

26 Sept. 2001

Authorized officer
Sune Söderling / MRo

Date of mailing of the international search report
13. 11. 2001

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